EX-10.1 2 ea127075ex10-1_hoth.htm SPONSORED RESEARCH AGREEMENT BY AND BETWEEN THE COMPANY AND THE GEORGE WASHINGTON UNIVERSITY

Exhibit 10.1

SPONSORED RESEARCH AGREEMENT
between

HOTH THERAPEUTICS, INC.
and
THE GEORGE WASHINGTON UNIVERSITY

This sponsored research agreement ("Agreement"), effective as of September 1, 2020 ("Effective Date"), is entered into by and between Hoth Therapeutics, Inc., a State of Nevada corporation, having offices at One Rockefeller Plaza Suite 1039, New York, NY 10020 ("Sponsor") and the George Washington University, a congressionally chartered nonprofit corporation located in Washington, DC ("GW"), each a "Party" and collectively the "Parties".

WITNESSETH:

WHEREAS, the research contemplated by this Agreement is of mutual interest and benefit to GW and Sponsor, and will further the instructional and research objectives of GW in a manner consistent with its mission;

NOW, THEREFORE, in consideration of the mutual covenants, agreements, representations and warranties of the Parties and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

ARTICLE I: Scope of Work

GW agrees to perform the work set forth in the Scope of Work appended hereto and incorporated as Appendix A (the "Project"). The Scope of Work shall not be changed except by duly executed amendment to this Agreement. To the extent there are any inconsistencies between the Scope of Work and this Agreement, this Agreement shall control.

ARTICLE II: Period of Performance

The period of performance for this Agreement shall commence on the Effective Date and shall continue through July 31, 2021 ("End Date"), unless the End Date is extended by mutual agreement in writing between the Parties, or unless this Agreement is earlier terminated as provided in Article XIV.

ARTICLE III: Project Direction

The research shall be supervised by Mona Zaghloul, PhD ("Principal Investigator"). Jeanne Jordan, PhD, will act as Co-Principal Investigator. If for any reason the Principal Investigator withdraws or is otherwise unable to continue to serve as Principal Investigator, GW shall appoint a new Principal Investigator, subject to the approval of Sponsor, which approval shall not be unreasonably withheld, delayed or conditioned. If the Parties are unable to agree on a successor Principal Investigator, either Party may terminate the Agreement pursuant to Article XIV herein.

ARTICLE IV: Consideration and Payment

As consideration and compensation for the research conducted under this Agreement as described in Appendix A, Sponsor agrees to pay GW on a cost-reimbursable basis for all direct and indirect costs incurred in the performance of the research, not to exceed [*]. GW may request additional funds from Sponsor, which Sponsor may elect to provide at its discretion. Any such additional funds shall be subject to the written mutual consent of the Parties.

Invoices shall be prepared in GW's standard format, and may be sent via e-mail or U.S. mail to the Sponsor representative identified in Article VI. Payments shall be made within thirty (30) days of receipt of invoice, and sent via wire or ACH transfer to (preferred payment method):

Beneficiary Account Number:
Beneficiary Account Name:
Beneficiary Address:
Bank Name:
Bank Address:
ABA # (for Wires):
ABA # (for ACH):
SWIFT#:
Remitters Text:

If payment is made by check, make checks payable to The George Washington University and mail checks to:

George Washington University-GCAS
PO Box 829896
Philadelphia, PA 19182-9896

If by overnight courier:

PNC Bank c/o George Washington University-GCAS
Lockbox Number 829896
312 W Route 38
Moorestown, NJ 08057
(571)553-4356
Email: ttaube@gwu.edu

A final financial accounting of all costs incurred and funds received shall be submitted to Sponsor within ninety (90) days of the End Date, along with any unexpended funds.

ARTICLE V: Technical Report

GW agrees to provide to Sponsor a final technical report, which shall summarize the research program accomplishments and significant research findings. No other reports or deliverables are required to be submitted. The final technical report shall be submitted to Sponsor within ninety (90) days of the termination or expiration of this Agreement.

ARTICLE VI: Notices

All notices and matters affecting the terms of this Agreement or the administration thereof shall be in writing and delivered by confirmed e-mail, or by certified mail, return receipt requested, and in each instance shall be deemed given upon receipt. Either Party may change its address for notices under this Agreement by giving written notice to the other Party by the means specified in this Article VI. All communications shall be sent to:

Sponsor:

Robb Knie, CEO
Hoth Therapeutics
One Rockefeller Plaza Suite 1039
New York, NY 10020
201-446-7900
robb@hoththerapeutics.com

GW:

Director, Sponsored Projects
The George Washington University
Office of the Vice President for Research
1922 F Street NW, 4th Floor
Washington, DC 20052
202-994-0728
osr@gwu.edu

ARTICLE VII: Confidential Information

a. During the term of this Agreement, each Party may be given access to proprietary information, technology, data, samples, inventions, software, know-how and/or trade secrets, business, financial, personnel, technical and scientific information, and commercialization, clinical and research strategies (hereinafter the "Confidential Information") of the other Party. The Party receiving such Confidential Information may use such Confidential Information only for the purposes provided for in this Agreement. The receiving Party shall not, at any time, use Confidential Information for any other purpose or disclose Confidential Information to third parties. Confidential Information does not include any information that the receiving Party can demonstrate:

(i) is or becomes publicly known and made generally available to the public through no fault of the receiving Party;

(ii) was already in the possession of the receiving Party at the time of disclosure by the disclosing Party, as evidenced by contemporaneous written records of the receiving Party;

(iii) becomes available to the receiving Party from a source other than the disclosing Party which source is not bound by any obligation of confidentiality to the disclosing Party in relation to such information;

(iv) is independently developed by the receiving Party after receiving the Confidential Information by personnel who have not had any access to any Confidential Information and without using or referring to the Confidential Information as demonstrated by contemporaneous records;

(v) is required to be disclosed pursuant to any legal, administrative or regulatory proceeding or requirement, provided, however, that the receiving Party, if legally permitted to do so, promptly provides to the disclosing Party prior written notice of any such requirement, such that the disclosing Party may seek a protective order or other appropriate remedy to prevent or limit such disclosure, and reasonable assistance in protecting the disclosing Party's Confidential information from public disclosure; or

(vi) is approved in writing for public release by the disclosing Party.

b. The disclosing Party shall clearly mark or label Confidential Information as "Confidential." If the Confidential Information is disclosed orally or visually, the disclosing Party shall identify it as such at the time of disclosure and shall confirm in writing within 10 days after disclosure the Confidential Information disclosed and the date of oral disclosure.

c. The receiving Party shall protect the confidentiality of the Confidential Information in at least the same manner that it protects the confidentiality of its own proprietary and confidential information, and in any event shall take all reasonable measures to prevent improper disclosure of the Confidential Information or any portion thereof.

d. The obligations set forth in this Article VII shall survive for a period of three (3) years after the expiration or early termination of this Agreement.

ARTICLE VIII: Export Control

Each Party shall comply with applicable U.S. export control requirements, including under the Export Administration Regulations ("EAR"), the International Traffic in Arms Regulations ("ITAR"), and the controls under the regulations of the Department of Energy and the Nuclear Regulatory Commission ("NRC").

Prior to one Party providing the other Party with technical data, technology, software, commodities, defense articles, or defense services that are subject to U.S. export controls, the disclosing Party will provide advance written notice to the receiving Party regarding the relevant export control jurisdiction and classification and the receiving Party must issue written approval to the disclosing Party prior to transmission to the receiving Party. Such notice is not required for the following:

a. Technology or software that arises during, or results from, fundamental research under EAR Section 734.8;

b. Information concerning general scientific, mathematical, or engineering principles commonly taught in schools, colleges, and universities under ITAR Section 120.10(b);

c. Information that is in the public domain under ITAR Section 120.11;

d. Information or software that: (1) is published under Section 734.7 of the EAR, (2) appears in a patent or patent application under EAR Section 734.3(b)(3)(iv), (3) is released by instruction in a catalog course or associated teaching laboratory of an academic institution under EAR Section 734.3(b)(3)(iii), (4) is non-proprietary system descriptions, or (5) telemetry data or items that are not subject to the EAR under Section 734.3(b)(2);

e. Basic marketing information on function or purpose or general system descriptions of ITAR-controlled defense articles; or

f. EAR99 technology, software, or commodities.

Notwithstanding any other provision of this Agreement, the receiving Party is under no obligation to accept from the disclosing Party technical data, technology, software, commodities, defense articles, or defense services that are subject to U.S. export controls.

ARTICLE IX: Publication

GW shall have the right to publish, disseminate, create derivative works or otherwise utilize any and all data and results of research created or collected in connection with this Agreement. GW shall furnish to Sponsor a copy of any proposed publication, thirty (30) days prior to submission for publication. At Sponsor's request, GW shall reasonably modify or correct the manuscript to prevent disclosure of any of Sponsor's Confidential Information. Under no circumstances shall Sponsor request GW to defer or to further delay the submission of a manuscript for publication beyond the review period of thirty (30) days. If no response is received by GW from Sponsor within the thirty (30) day review period, it is conclusively presumed that publication may proceed without any additional obligation placed upon GW. Each publication shall appropriately acknowledge Sponsor's partial or complete support of the research work to be published (as applicable).

ARTICLE X: Intellectual Property

a. Definitions

"GW Background Intellectual Property" means all technical information, data, and tangible material, whether or not patentable or copyrightable, that GW conceived, reduced to practice, made or created prior to the Effective Date of this Agreement or outside the scope of this Agreement.

"GW Project IP" means all Project Intellectual Property conceived and reduced to practice or created solely by GW personnel.

"Joint Project IP" means all Project Intellectual Property conceived and reduced to practice or created jointly by Sponsor and GW.

"Project Intellectual Property" means all technical information, inventions, developments, discoveries, methods, processes, and techniques that are conceived and reduced to practice or created in conducting the Project during the term of the Agreement, and all formulas, data, information, works of authorship, trademarks, service marks, mask works, trade secrets, moral rights, patent rights (including, but not limited to, patent applications and disclosures), and all material and information, including computer software, whether or not patentable or copyrightable, and all other intellectual property rights recognized in any country or jurisdiction in the world that are created or collected in conducting the Project during the term of this Agreement.

"Sponsor Background Intellectual Property" means all technical information, data, and tangible materials, whether or not patentable or copyrightable, that the Sponsor conceived, reduced to practice, made or created prior to the Effective Date of this Agreement or outside the scope of this Agreement.

"Sponsor Project IP" means all Project Intellectual Property conceived and reduced to practice or created solely by Sponsor personnel.

b. Ownership of Project IP. All right, title and interest in and to GW Project IP will remain exclusively with GW. All right, title and interest in and to Sponsor Project IP will remain exclusively with Sponsor. All rights, title and interest in Joint Project IP are jointly owned by GW and Sponsor whereby the parties have an undivided interest in the entirety of all Joint Project IP.

c. License to GW. Sponsor hereby grants to GW a fully-paid up, non-exclusive, royalty-free license to Sponsor Project IP for GW's non-commercial internal research and educational purposes with the right to permit other not-for-profit institutions to use the Sponsor Project IP for their own non-commercial internal educational and research purposes.

d. License to Sponsor. GW hereby grants to Sponsor a non-exclusive, royalty-free, license to GW's rights in GW Project IP for Sponsor's non-commercial internal research use only, without the right to sublicense or redistribute.

e. Ownership of Background Intellectual Property. GW has and retains all right, title and interest in GW Background Intellectual Property and the ownership of such property is not affected by this Agreement. Sponsor retains all right, title and interest in Sponsor Background Intellectual Property and the ownership of such property is not affected by this Agreement.

ARTICLE XI: Equipment and Supplies

Title to any equipment or supplies purchased or manufactured in the performance of this Agreement shall vest in GW upon acquisition.

ARTICLE XII: Warranties

ANY PROJECT INTELLECTUAL PROPERTY, PATENT RIGHTS, LICENSED PRODUCTS AND ANY OTHER TECHNOLOGY LICENSED UNDER THIS AGREEMENT ARE PROVIDED ON AN "AS IS" BASIS. UNIVERSITY MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY WARRANTY OF ACCURACY, COMPLETENESS, PERFORMANCE, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, COMMERCIAL UTILITY, NON-INFRINGEMENT, ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE, OR TITLE.

Each party shall be responsible for any and all costs, damages, claims, liabilities or judgments which arise as a result of the negligence or intentional wrongdoing of its employees or other agents. GW WILL NOT BE LIABLE TO SPONSOR , ITS AFFILIATES, SUBLICENSEES, SUCCESSORS OR ASSIGNS, OR ANY THIRD PARTY WITH RESPECT TO ANY CLAIM: ARISING FROM SPONSOR'S USE OF ANY PROJECT INTELLECTUAL PROPERTY, PATENT RIGHTS, LICENSED PRODUCTS OR ANY OTHER TECHNOLOGY LICENSED UNDER THIS AGREEMENT; OR ARISING FROM THE DEVELOPMENT, TESTING, MANUFACTURE, USE OR SALE OF LICENSED PRODUCTS. GW WILL NOT BE LIABLE TO SPONSOR, ITS AFFILIATES, SUBLICENSEES, SUCCESSORS OR ASSIGNS, OR ANY THIRD PARTY FOR LOST PROFITS, BUSINESS INTERRUPTION, OR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES OF ANY KIND.

ARTICLE XIII: Indemnification

Each Party shall defend, indemnify and hold the other Party, its officers, trustees, agents and employees harmless from and against any and all liability, loss, expense (including reasonable attorneys' fees) or claims for injury or damages arising out of the performance of this agreement, but only in proportion to and to the extent of any negligence or fault by the indemnifying party, its officers, agents or employees. The obligations under this paragraph shall survive the termination of this agreement.

ARTICLE XIV: Termination

This Agreement may be terminated by either Party upon thirty (30) days written notice to the other Party. Upon receipt of notice of termination, GW shall proceed to terminate any outstanding commitments and stop the research as soon as practicable. GW shall be reimbursed for non-cancellable obligations incurred prior to the effective date of termination, including the full cost of each employee, student, and faculty member supported hereunder, through the end of such commitments. Nothing in this paragraph is intended to abrogate the Parties' rights to mutually terminate this Agreement on such terms as may be agreed upon. GW will furnish any necessary report of research completed or in progress through the date of termination.

ARTICLE XV: Governing Law and Dispute Resolution

a. Governing Law. This Agreement shall be governed and construed, and the rights and obligations of the Parties shall be determined, in accordance with the laws of the District of Columbia, without regard to conflict of laws issues.

b. Dispute Resolution. Any dispute arising from this Agreement shall be resolved by good faith negotiations between the Parties. If the Parties cannot resolve the dispute via negotiations, either Party may file suit solely in the local or federal courts of the District of Columbia, and all Parties hereby consent to the personal jurisdiction and venue of such courts for any such action, regardless of where they may reside or work at the time of such dispute.

ARTICLE XVI: Use of Names

Neither Party will use the name, logos, trademarks, or other identifiers of the other Party, or the names of the other Party's employees, without the prior written permission of the other Party in each instance. For the avoidance of doubt, GW is permitted to disclose the existence of this Agreement in any GW listing of sponsored research projects.

ARTICLE XVII: Independent Inquiry.

Nothing in this Agreement shall be construed to limit GW from engaging in similar or other inquiries made independently or with parties other than Sponsor.

ARTICLE XVIII: General Provisions

a. Independent Contractor. The Parties are strictly independent contractors and are not, in any way, employees, partners, joint venturers or agents of the other and shall not hold themselves out to be the agent, employer, or partner of the other. Nothing contained herein shall be construed to give either Party any authority, right or ability to bind or commit the other in any way. Neither shall, in any way, bind the other in any way unless such Party has received the written consent of the other.

b. Modification. No amendment, alteration, or modification of this Agreement shall be valid unless executed in writing by authorized signatories of both Parties.

c. Assignment. Neither Party may assign or subcontract the rights or obligations under this Agreement without the other Party's prior written consent.

d. Force Majeure. Neither Party shall be responsible for any failure or delay in its performance under this Agreement due to causes beyond its reasonable control, including but not limited to labor strife including strikes, lockouts, shortages of or inability to obtain labor, energy, raw materials or supplies, war, riot, acts of terrorism, civil unrest, an act of God (including but not limited to fire, flood, earthquakes or other natural disasters) or governmental action (including but not limited to any law, regulation, Decree or denial of visas or residence permits). In the event that either Party wishes to invoke force majeure, that Party shall send written notice of such event to the other Party. In the event that a force majeure event prevents either Party's performance for a period of thirty (30) days or more, either Party shall be entitled to terminate this Agreement upon written notice to the other Party. The provisions of this paragraph shall not apply to the payment of any amount due for research already performed. The Parties will work in good faith to prevent one Party from unfairly benefitting from the force majeure event.

e. Waivers. There shall be no waiver of any term, provision or condition of this Agreement unless the waiver is set forth in a written document signed by the waiving Party. No such waiver shall be deemed to be or construed as a continuing waiver of any such term, provision or condition unless the written waiver states to the contrary. The waiver by either Party of its rights or remedies under this Agreement in a particular instance shall only apply to matters arising from or in connection with this Agreement. Either Party's failure to enforce any provision shall not prejudice such Party from later enforcing or exercising the same or any other provision of the Agreement.

f. Titles. All titles and article headings contained in this Agreement are used only for reference and convenience and are not to define, limit, extend or otherwise describe the scope of the Agreement or the meaning or intent of its provisions.

g. Severability. If any part, term or provision of this Agreement is held unlawful by an adjudicative body with jurisdiction over the Parties, the validity of the remaining portions or provisions shall not be affected and will be interpreted so as to best effect the original intent of the Parties.

h. Survivorship. The terms of Articles VII - XVIII shall survive the expiration or termination of this Agreement.

i. Counterparts. This Agreement may be executed in one or more counterparts, each of which will be an original and all of which will constitute together the same document.

j. Electronic Signature. The Parties acknowledge and agree that this Agreement may be executed or accepted using electronic or facsimile signatures, and that such a signature shall be legally binding to the same extent as a written signature by a Party's authorized representative. Each Party waives any legal requirement that this Agreement be embodied, stored or reproduced in tangible media, and agrees that an electronic reproduction shall be given the same legal force and effect as a signed writing.

k. Entire Agreement. This Agreement and all attachments and appendices constitutes the entire understanding between the Parties with respect to the subject matter hereof and may not be amended except by an agreement signed by authorized representatives of Sponsor and GW.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement on the dates specified below.

SPONSOR	THE GEORGE WASHINGTON UNIVERSITY
By: /s/ Robb Knie	By: /s/ Charles T. Maples
Name: Robb Knie	Name: Charles T. Maples
Title: CEO	Title: Sr. Contracting Officer, Sponsored Projects
Date: 9-17-20	Date: 9-14-20

THE GEORGE WASHINGTON UNIVERSITY

WASHINGTON, DC

Appendix A

Office of the Vice President for Research

September 2, 2020

Hayley Springer
Vice President of Operations
Hoth Therapeutics
646-756-2997
hayley@hoththerapeutics.com

Dear Ms. Springer,

This letter declares The George Washington University's intent to collaborate in the project entitled "A Smartphone-based Direct Virus Sensing System for SARS-CoV-2," through Hoth Therapeutics with Dr. Mona Zaghloul, Professor, for the George Washington University.

Attached is a description of the effort and resources that The George Washington University (GW) will commit to this project, along with a budget. The proposed period of performance is from 9/1/2020 to 7/31/2021. The total budget for the George Washington University is [*].

Should you have any technical questions, please contact Dr. Mona Zaghloul at 202-994-3772 or zaghloul@gwu.edu. Contractual matters should be addressed to me, at 202-994-0728 or email at osr@gwu.edu.

Sincerely,

Sylvia Ezekilova
Interim Director, Office of Sponsored Projects

1922 F Street, NW – 4th Floor | Washington, DC 20052
t 202-994-0728 | **f** 202-994-9137 | research.gwu.edu

Project Title:

A Smartphone-based Direct Virus Sensing System for SARS-CoV-2

The objective of this funded project is to design and assess the analytical performance of the Au Nano sensor from Dr. Zaghloul's lab that directly detects SARS-CoV-2 virus and distinguishing that binding from other human coronaviruses (i.e., 229e and OC43). The sensor developed is a nanohole array (NHA)-based plasmonic sensing system. It shows high levels of sensitivity and selectivity for detecting and analyzing analytes, especially mixtures of chemicals/biochemicals.

We have filed a joint patent between GWU and NIST for the technology (US2019277762A1). This proposal will leverage this patented technology for an infectious disease application. We propose to build microfluidic channel on top of the NHA for sample input and fluid output to detect SARS-CoV-2 virus and distinguish that the binding analyte from other human coronaviruses (i.e., 229e and OC43) The proposed work is summarized in the following steps:

Step1: Guide and immobilize inactivated virus contained within a liquid to the sensing area through a microfluidic channel.

Step 2: Detect the virus using the NHA sensing system

The most challenging thing is how to identify and combine SARS-CoV-2 on the NHA sensor to eliminate the impact of other strains of coronavirus on the experiment as much as possible. Because the specificity of binding is critical and must be thoroughly assessed so to reduce the risk of false-positive results being generated from the binding of a non-SARS-CoV-2 coronavirus. If this specificity problem can be solved, combined with our existing high-sensitivity NHA sensor system, it will greatly increase the accuracy and efficiency of SARS-CoV-2 virus detection. The simple to use, low-cost device with its high-efficiency platform will be very competitive and could even replace the current nucleic acid detection methods. Its huge commercial potential lies in the possibility of developing testing applications for detecting a variety of different infectious pathogens in the future.

The NHA sensing platform works in optical mode. Due to the specially designed patterns (nanoholes with a diameter of 200 nm and a period of 400 nm), our NHA sensor shows a plasmonic spectrum in the visible wavelength. When the virus is detected, the local refractive index will change due to the existence of the virus. As a result, the visible spectrum of the sensor will shift, i.e., the color of the sensor will slightly change, which can be captured by a CMOS camera. In our previous work, a smartphone camera is powerful enough to monitor the slight color change. Our procedure will be first testing the sensor using a spectrometer to record the spectra of the sensor. The spectra will be used as references to calculate the local refractive index change caused by the virus. After that, we will use a CMOS camera to acquire images of the bare sensor, sensor with receptors, and sensor with the virus. The acquired images will be labeled with the corresponding conditions and saved in the server for system training.

Step 3: Design and train an ANN-based algorithm to classify the SARS-CoV-2 virus

We will use open-source machine learning libraries such as TensorFlow and Pytorch to train the ANN with the images acquired in S2b. The purpose of this step is to classify SARS-CoV-2 with more than 90% accuracy. We will modify the ANN structure and optimize the hyperparameters to achieve a 90% accuracy of COVID-19 recognition using machine learning and a Smartphone. developed a nanohole array (NHA)-based plasmonic sensing system.

Assay Design:

The final design will have a sensor containing two to three channels. Each channel will be functionalized with one of the following reagents:

- ACE2 protein (binds SARS-C0V-2)
- Anti-SARS-CoV-2 receptor binding domain (RBD) S1 spike protein (binds SARS-CoV-2)
- Anti-human IgA antibody (Internal control if oral saliva samples are tested)

Two channels are designed to bind SARS-CoV-2 virus particles from saliva specimens. We may find that one of these two proteins (ACE2 or anti-RBD antibody) has significantly better analytical performance characteristics than the other. In that case, we would design the device with one channel for virus binding and one channel for the internal control (IC). The IC is critical for evaluating specimen adequacy. For the SARS-CoV-2 test result to be considered valid, the IC result needs to be positive. This is especially important when SARS-CoV-2 virus is not detected in the specimen, or is present below the limit of detection, so you can have confidence to say a negative result is a true negative and not a false negative.

We will begin by focusing our efforts on assessing the ability of ACE2 protein and anti-RBD of S1 spike protein to bind to the Au nanosensor. To accomplish this, we will use fluorescently-labeled proteins so that the extent of the coating process can be visualized using a fluorescent microscope (GWU Imaging Facility, B2 level, SEH building). We have found commercial sources of the following fluorescently-labeled reagents:

- FITC-labeled anti-RBD S1 spike protein nanobody
- FITC-labeled anti-human IgA1 Fc antibody (mouse monoclonal or rabbit polyclonal designed for ELISA-based tests)

We have not yet found a source of fluorescently-labeled ACE2 protein. This situation may require my lab or a commercial vendor to conjugate a fluorophore to a purified source of human ACE2 protein.

Once we demonstrate adequate binding of these various proteins to the Au nanosurface, we will proceed to functionalize the Au nanosensor using unlabeled proteins. These proteins include:

- Purified recombinant human ACE2 protein (SARS-CoV-2 binding)
- Anti-RBD S1 spike protein nanobody (SARS-CoV-2 binding)
- Anti-human IgA antibody (IC)

We need to determine the optimal concentrations of the ACE2 protein and the anti-RBD S1 spike protein nanobody to use to coat the channels for optimal sensitivity. Depending upon the stock concentration of the reagent, serial 2-fold, 5-fold or 10-fold dilutions of the two coating proteins will be used to functionalize the surface of the Au nanosensor. These two reagents will be assessed individually when determining the optimal concentrations to use. Inactivated virus will then be added to these functionalized Au nanosensors to look for a change in wavelength as an indicator of binding of the virus to the protein. We have chosen to work with gamma irradiated SARS-CoV-2 virus rather than heat inactivated virus so as to avoid working with denatured viral proteins, which could negatively impact binding of virus with the ACE2 protein and the SARS-CoV-2 anti-RBD antibody.

Serial 10-fold dilutions of each virus stock will be made I 1X PBS, and then tested in triplicate on these functionalized Au nanosensors to determine limit of detection for this device. Specificity of binding to these functionalized proteins will be assessed using similar concentrations of UV-irradiated cultured stocks of common human coronaviruses (229E and OC43). Gamma irradiated human coronavirus 229E and OC43 are not available, so UV irradiated virus will be used instead to perform the specificity studies.

Once we have determined limit of detection for SARS-CoV-2 virus, and assessed assay specificity, we will work on designing the internal control channel(s). Here we will work in parallel functionalizing one channel on the device using fluorescently labeled reagents to assess coating of the Au surface (see list above). Once that is established, we will coat the Au surface with unlabeled reagents; mouse anti-human IgA antibody. Again, serial 2-fold, 5-fold or 10-fold dilutions of each of these antibodies will be made for functionalizing the Au nanosensor. We will begin using purified human IgA to do these experiments. After those experiments, we can introduce working with saliva matrices for detection of human IgA.

Ultimately, this device is being designed to be used both as a point of care test and for at home testing to detect SARS-CoV-2 virus antigen(s). A breath sample type (or equivalent) can also be investigated for technical feasibility, but not required under the existing scope of work.

Rationale for choosing S1 domain, which contains the receptor binding domain (RBD) over the S2 domain of the spike protein in designing assay:

There is less amino acid homology for S1 compared to S2 between SARS-CoV and SARS-CoV-2 (64% vs. 91%).

The S1 subunit is found not only on intact virus (prefusion) prior to binding to ACE2 receptors, but can be found as free S1 subunits that are shed from the virus after binding to the ACE2 receptors (postfusion).

	Title:	**A Smartphone-based Direct Virus Sensing System for SARS-CoV-2**						
	PI:	**Mona Zaghloul**						
	Sponsor:	**Hoth Therapeutics**						
	Period of Performance:	**9/1/2020 to 7/31/2021**						
							12/01/2020 – 07/31/2021 **Period 1**	**TOTAL**
A.	**Senior Personnel***							
		Base Salary	Monthly	Effort	Appointment	Person Months		
	PI (SMR): Mona Zaghloul							
	Co-PI (CY): Jeanne Jordan							
						Total Senior Personnel	[*]	[*]
B.	**Other Personnel***							
		Base Salary	Monthly	Effort	Appointment	Person Months		
	Research Scientist:							
						Total Senior Personnel	[*]	[*]
C.	**Graduate Research and Temporary Personnel***							
		Base Salary	Monthly	Effort	Appointment	Person Months		
	Graduate Research Assistant							
	Graduate Research Assistant							
	Graduate Research Assistant							
						Total Graduate Research and Temporary Personnel	[*]	[*]
						TOTAL SALARIES & WAGES		
D.	**Fringe Benefits****							
	Senior Personnel							
	Other Personnel							
	Graduate Research and Temporary Personnel							
						Total Fringe Benefits	[*]	[*]
						TOTAL SALARIES, WAGES, & FRINGE BENEFITS		
E.	Other Direct Costs - included in MTDC							
	Materials & Laboratory Supplies							
	Cleanroom							
						Total Other Direct Costs – included in MTDC	[*]	[*]
F.	**Other Direct Costs - not included in MTDC**			Credits	Rate	# of Students		
	Tuition							
						Total Other Direct Costs – not included in MTDC	[*]	[*]
G.	***Modified Total Direct Costs (MTDC)***							
H.	**Total Direct Costs**							
I.	**Indirect Costs (F&A, Facilities & Administrative Costs)**							
	Rate Negotiated with DHHS***							
J.						**TOTAL REQUESTED**	[*]	[*]

* Salaries are projected to increase 4% effective January 1, annually, except on NIH capped salaries.

** Fringe is calculated at 25.10% for regular staff and 6.50% for temporary staff, per DHHS Agreement, dated 1/14/2020, effective through 6/30/2021, provisional thereafter

*** Indirect costs are calculated at 59.5% MTDC- On Campus, per DHHS Agreement dated 1/14/2020,effective through 6/30/2019, provisional thereafter

BUDGET JUSTIFICATION

Senior Personnel –

Dr. Mona Zaghloul will be supported on this grant as the Principal Investigator overseeing the work performed and supervising personnel.

The PI will take 100% of two summer months effort, or the equivalent of 2 person months. Professor Zaghloul will supervise the clean room work to fabricate the microfluidic parts to fit the gold Nano-sensor to be able to add the protein ACE2 and antibody protein on top if the sensor to attach to the sensor surface. She will also supervise the extra sensors fabrication as needed. She will work on generating several data measurements in the laboratory to be able to identify the virus. She will work with her students to develop algorithms to transfer the data. She will work with her students to do all required tasks.

Dr. Jeanne Jordan will be supported on this grant as a Co-Principal Investigator.

The Co-PI will take 25% of 8 calendar months or the equivalent of 2 person months. Dr. Jordan will work to develop Assay Design needed to detect the presence of virus within the biologic sample. The final design will integrate a sensor containing two to three channels. Each channel will be functionalized with one of the specified reagents, she will begin her experiments with fluorescently labeled reagents and work with the Imaging Facility in B2 SEH to verify the functionalization of the proteins to the gold nanosurface. She will then work with Dr. Zaghloul and her students to verify the attachment of the microfluidic device which will deliver the biologic specimen to the top of the Nano sensor and verify the functionalization of the sensor surface and verify the attachment of the virus.

Other Personnel –

We are also requesting support for a research scientist, Dr. Kamwing Jair, who will take 40% of 8 months effort. He will work closely with Dr. Jordan and support her work in her laboratory to optimize assay conditions to achieve the most sensitive and specific assay possible for direct detection of the SARS-CoV-2 virus from the biological specimen. We will need to assess analytical performance criteria of the assay including sensitivity and specificity. Limit of detection (LOD) of the SARS-CoV-2 virus within a relevant sample matrix will also need to be determine. Lastly, we will need to build an internal control into the device, in order to assess the validity of test results.

Graduate Research and Temporary Personnel –

Three graduate research assistants (GRAs) will be 50% full time equivalent (FTE) and be supported for 6 academic and 2 summer months. The GRAs will work at Dr. Zaghloul laboratory and at the SHE clean room to fabricate the microfluidic channels, and to fabricate the new sensors as needed. The measure and characterize the sensors and the microfluidic part

Fringe Benefits –

Fringe benefit rates of [*]% for full-time employees and [*]% for temporary employees and students is fixed through 6/30/2021, and provisional thereafter per DHHS agreement dated 1/14/2020.

Other Direct Costs – included in MTDC –

We are requesting funds for needed materials to use in the fabrication at the SHE clean room, for needed reagents to functionalize the gold Nano sensor as well as the materials used in the measuring of the microfluidic and the gold Nano sensor. Spectrometer is needed to measure the spectrum of the plasmonic sensor and to identify the attachment of the virus to the sensor.

Other Direct Costs – not included in MTDC –

The project will support two GRAs with 9 credit hours of tuition per year at [*] per credit

Modified Total Direct Costs (MTDC) –

Total Direct Costs –

Indirect Costs (Facilities & Administrative Costs) –

The F&A rate of [*]% is predetermined through 6/30/2019 and provisional thereafter per DHHS agreement dated 01/14/2020.

TOTAL REQUESTED – [*]

COLLEGES AND UNIVERSITIES RATE AGREEMENT

EIN:
ORGANIZATION:
George Washington University
44983 Knoll Square, 2nd Floor
Ashburn, VA 20147

DATE: 01/14/2020
FILING REF.: The preceding agreement was dated 01/22/2019

The rates approved in this agreement are for use on grants, contracts and other agreements with the Federal Government, subject to the conditions in Section III.

SECTION I: INDIRECT COST RATES

RATE TYPES: FIXED FINAL PROV. (PROVISIONAL)PRED. (PREDETERMINED)

TYPE	EFFECTIVE PERIOD FROM	TO	RATE (%)	LOCATION	APPLICABLE TO
PRED.	07/01/2015	06/30/2016		On-Campus	Organized Research (1)
PRED.	07/01/2015	06/30/2016		On-Campus	Organized Research (2)
PRED.	07/01/2016	06/30/2019		On-Campus	Organized Research (3)
PRED.	07/01/2015	06/30/2019		Off-Campus	Organized Research – Biostatistics (4)
PRED.	07/01/2015	06/30/2019		Off-Campus	Organized Research
PRED.	07/01/2015	06/30/2019		On-Campus	Other Sponsored Activities
PRED.	07/01/2015	06/30/2019		Off-Campus	Other Sponsored Activities
PROV.	07/01/2019	Until Amended			Use same rates and conditions as those cited for fiscal year ending June 30, 2019.

*BASE

Modified total direct costs, consisting of all salaries and wages, fringe benefits, materials, supplies, services, travel and subgrants and subcontracts up to the first [*] of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, student tuition remission, rental costs of off-site facilities, scholarships, and fellowships as well as the portion of each subgrant and subcontract in excess of [*].

(1) Rates apply to University projects, excluding Medical Center Schools.
(2) Rates apply to Medical Center Schools, which includes the School of Medicine and Health Sciences, School of Public Health and Health Services, and the School of Nursing, excluding University.
(3) Effective 10/29/2015, school will utilize one blended organized research rate for the University Projects and Medical Center for fiscal year starting 7/1/2016.
(4) Organized Research Biostatistics rates exclude all Departmental Administrative Costs other than the Deans' office.

SECTION I: FRINGE BENEFIT RATES**

TYPE	FROM	TO	RATE (%)	LOCATION	APPLICABLE TO
FIXED	7/1/2020	6/30/2021		All	Regular Employees
FIXED	7/1/2020	6/30/2021		All	Temps & Students
PROV.	7/1/2021	Until amended			Use same rates and conditions as those cited for fiscal year ending June 30, 2021.

** DESCRIPTION OF FRINGE BENEFITS RATE BASE:

Salaries and wages.

SECTION II: SPECIAL REMARKS

TREATMENT OF FRINGE BENEFITS:

The fringe benefits are charged using the rate(s) listed in the Fringe Benefits Section of this Agreement. The fringe benefits included in the rate(s) are listed below.

TREATMENT OF PAID ABSENCES

Vacation, holiday, sick leave pay and other paid absences are included in salaries and wages and are claimed on grants, contracts and other agreements as part of the normal cost for salaries and wages. Separate claims are not made for the cost of these paid absences.

OFF-CAMPUS DEFINITION: For all activities performed in facilities not owned by the institution and to which rent is directly allocated to the project(s) the off-campus rate will apply. Grants or contracts will not be subject to more than one F&A cost rate. If more than 50% of a project is performed off-campus, the off-campus rate will apply to the entire project.

Fringe Benefits include: FICA, Retirement, Disability Insurance, Life Insurance, Tuition Remission, Workers' Compensation, Unemployment Insurance, Health & Dental Insurance, Death Benefits, Sabbatical Leave, and Post Retirement Benefits.

An equipment means an article of nonexpendable tangible personal property having a useful life of more than one year, and an acquisition cost of [*] or more per unit.

Next Fringe Benefits rates proposal for fiscal year ending 06/30/2020 is due in our office by 12/31/2020.

This rate agreement updates the Fringe Benefits rates section only.

SECTION III: GENERAL

A. LIMITATIONS:

The rates in this Agreement are subject to any statutory or administrative limitations and apply to a given grant, contract or other agreement only to the extent that funds are available. Acceptance of the rates is subject to the following conditions: (1) Only costs incurred by the organization were included in its facilities and administrative cost pools es finally accepted: such costs are legal obligations of the organization and are allowable under the governing cost principles; (2) The same costs that have been treated as facilities and administrative costs are not claimed as direct costs; (3) Similar types of costs have been accorded consistent accounting treatment; and (4) The information provided by the organization which was used to establish the rates is not later found to be materially incomplete or inaccurate by the Federal Government. In such situations the rate(s) would be subject to renegotiation at the discretion of the Federal Government.

B. ACCOUNTING CHANGES:

This Agreement is based on the accounting system purported by the organization to be in effect during the Agreement period. Changes to the method of accounting for costs which affect the amount of reimbursement resulting from the use of this Agreement require prior approval of the authorized representative of the cognizant agency. Such changes include, but are not limited to, changes in the charging of a particular type of cost from facilities and administrative to direct. Failure to obtain approval may result in cost disallowances.

C. FIXED RATES:

If a fixed rate is in this Agreement, it is based on an estimate of the costs for the period covered by the rate. When the actual costs for this period are determined, an adjustment will be made to a rate of a future year(s) to compensate for the difference between the costs used to establish the fixed rate and actual costs.

D. USE BY OTHER FEDERAL AGENCIES:

The rates in this Agreement were approved in accordance with the authority in Title 2 of the Code of Federal Regulations, Part 200 (2 CFR 200), and should be applied to grants, contracts and other agreements covered by 2 CFR 200, subject to any limitations in A above. The organization may provide copies of the Agreement to other Federal Agencies to give them early notification of the Agreement.

E. OTHER:

If any Federal contract, grant or other agreement is reimbursing facilities and administrative costs by a means other than the approved rate(s) in this Agreement, the organization should (1) credit such costs to the affected programs, and (2) apply the approved rate(s) to the appropriate base to identify the proper amount of facilities and administrative costs allocable to these programs.

BY THE INSTITUTION:	ON BEHALF OF THE FEDERAL GOVERNMENT:
George Washington University	DEPARTMENT OF HEALTH AND HUMAN SERVICES
_____	_____
(INSTITUTION)	(AGENCY)
_____	_____
(SIGNATURE)	(SIGNATURE)
_____	_____
(NAME)	(NAME)
_____	_____
(TITLE)	(TITLE)
_____	_____

(DATE)

(DATE)

HHS REPRESENTATIVE: _____

TELEPHONE: _____

THE GEORGE WASHINGTON UNIVERSITY
ADMINISTRATIVE DATA SHEET

EIN **DUNS #043990498** **CAGE Code#4L405**
FICE #001444 **NAICS 611310** **Congressional District 01**

Applicant Organization: The George Washington University
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(202) 994-0728
Email: osr@gwu.edu

*Address all **billing matters** and mail **checks** to:*
George Washington University— GCAS
PO Box 829896
Philadelphia, PA 19182-9896

Overnight Courier Deliveries:
PNC Bank c/o George Washington University—GCAS
Lockbox Number
525 Fellowship Road, Suite 330
Mt. Laurel, NJ 08054-3415
(571) 553-4356
Email: ttaube@gwu.edu

Preferred Payment Method: Payment by **ACH and Wire transfers** should be sent to:

Beneficiary Acct No
Beneficiary Acct Name:
Beneficiary Address:
ABA # for ACH:
ABA # for Wires:
SWIFT#

If necessary, make checks payable to: The George Washington University
Credit to: Award/Invoice#

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Cognizant Audit Agency: DHHS, Region III
330 Independence Ave, SW, Rm 1067
Washington, DC 20201-0003
(301) 492-4855

The George Washington University has the necessary financial capacity, working capital and other resources to undertake the project without assistance from any other outside source.

GW policy prohibits acceptance of projects which prevent the open dissemination of research results or which restrict the access by the academic community to research programs of its students. Under this policy, the results of University research projects must be publishable and researchers must be permitted to present their results at symposia and professional meetings, and to publish in journals, theses or dissertations, or otherwise of their own choosing, the methods and results of such projects.

[a] Authorized Organizational Representative